UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JEFFREY THELEN,

Plaintiff,

v. Case No: 8:20-cv-1724-TPB-JSS

SOMATICS, LLC, and
ELEKTRIKA, INC.,

Defendants.
_____ /

ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

This matter is before the Court on the "Motion by Somatics, LLC for Final Summary Judgment," filed on November 22, 2022. (Doc. 78). Plaintiff filed a memorandum in opposition to the motion on January 10, 2023. (Doc. 99). Defendant Somatics, LLC, filed a reply in support of its motion on January 24, 2034. (Doc. 124).[1] Upon review of the motion, response, reply, court file, and the record, the Court finds as follows:

Background

Plaintiff Jeffrey Thelen has suffered from severe depression and other mental health issues for many years, resulting in hospitalization on more than one

[1] Somatics filed a corrected version of its motion shortly after filing the original version. *See* (Doc. 79). Defendant Elektrika, Inc, filed a motion for summary judgment on December 1, 2023. *See* (Docs. 88, 93). Elektrika, Inc. and Plaintiff have filed a notice of settlement, and Elektrika's motion is therefore no longer at issue. However, because Somatics' motion incorporates Elektrika's arguments by reference, this Order addresses points made by Elektrika as well as by Somatics. This written opinion supplements the Endorsed Order on Somatics' motion entered on May 3, 2023. (Doc. 154).

occasion. From May 2014 to July 2016, he received over 90 electro-convulsive therapy ("ECT") treatments at a CHI Health hospital in Omaha, Nebraska, using a Thymatron IV ECT device manufactured and sold by Defendant Somatics, LLC. Plaintiff alleges that despite knowing of the substantial risks associated with ECT treatment, Somatics failed to warn Plaintiff of these risks. Plaintiff alleges that the ECT treatments caused permanent neurological injury, including permanent memory loss and brain damage.

On July 24, 2020, Plaintiff filed this product liability suit under various legal theories. The remaining claims against Somatics are negligence (Count I), strict liability (Count II), and breach of express warranty against Somatics (Count IV). Somatics has moved for summary judgment on all claims against it.

Legal Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A properly supported motion for summary judgment is not defeated by the existence of a factual dispute. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Only the existence of a genuine issue of material fact will preclude summary judgment. *Id.*

The moving party bears the initial burden of showing that there are no genuine issues of material fact. *Hickson Corp. v. N. Crossarm Co., Inc.*, 357 F.3d 1256, 1260 (11th Cir. 2004). When the moving party has discharged its burden, the nonmoving party must then designate specific facts showing the existence of

genuine issues of material fact. *Jeffery v. Sarasota White Sox, Inc.*, 64 F.3d 590, 593-94 (11th Cir. 1995). If there is a conflict between the parties' allegations or evidence, the nonmoving party's evidence is presumed to be true and all reasonable inferences must be drawn in the nonmoving party's favor. *Shotz v. City of Plantation*, 344 F.3d 1161, 1164 (11th Cir. 2003).

Where, as here with respect to Somatics' statute of limitation defense, the moving party will bear the burden of proof on an issue at trial, demonstrating the absence of a genuine issue of material fact requires the submission of credible evidence that, if not controverted at trial, would entitle the moving party to a directed verdict on that issue. *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir. 1993). Only if the moving party meets that burden is the non-moving party required to produce evidence in opposition. *Chanel, Inc. v. Italian Activewear of Fla. Inc.*, 931 F.2d 1472, 1477 (11th Cir. 1991). Summary judgment should be denied unless, on the record evidence presented, a reasonable jury could not return a verdict for the non-moving party. *Id.*; *see also Fitzpatrick*, 2 F.3d at 1115-16.

Analysis

Statute of Limitation

Somatics argues that Plaintiff's claims are barred by Nebraska's four-year statute of limitation for product liability claims. Neb. Rev. Stat. § 25-224(1).[2] Under Nebraska law, the limitation period begins to run from the time the plaintiff

[2] The parties have relied on Nebraska law as governing the substantive claims and defenses at issue in this motion, and the Court agrees Nebraska law governs.

discovered or should have discovered the existence of the injury. *See, e.g.*, *Thomas v. Countryside of Hastings, Inc.*, 524 N.W.2d 311, 313 (Neb. 1994). Plaintiff filed suit on July 24, 2020. Accordingly, his claims are barred if he knew or should have known of the injury before July 24, 2016.

Somatics argues that the limitation period began to run in June 2015 when Plaintiff noticed he had lost some memories, and suspected this problem might be related to the ECT treatments. Accordingly, Somatics argues, Plaintiff knew he had suffered an injury in June 2015, the limitation period began to at that time, and his claims are time-barred.

However, the Supreme Court of Nebraska has noted that the limitation period may begin to run at different times for different injuries. *See Condon v. A. H. Robins Co.,* 349 N.W.2d 622, 623 (Neb. 1984). Plaintiff's claims in this suit are not based on a temporary loss of memory but on permanent or persistent memory loss and brain damage. The record in this case presents issues of fact as to whether Plaintiff was on notice of those injuries outside the limitation period. Among other things, the consent forms Plaintiff signed prior to treatment described short term memory loss as merely a "side effect" of treatment, but described permanent memory loss as a "risk" and as "rare," and said nothing at all about brain damage. Plaintiff testified in deposition that he raised his concerns about memory loss with his treating physician, Dr. Sharma, who responded that this was "impossible." Under the circumstances presented here, it cannot be said as a matter of law that Plaintiff should have discovered he had suffered an injury in the form of permanent

memory loss and brain damage, as opposed memory loss as a temporary side effect of treatment.

Somatics argues that once a party is on notice of some injury resulting from the defendant's act, the limitation period begins to run at once and does not wait on the plaintiff's learning the full extent or all the details of the injury. *See, e.g.*, *Minzel v. Ethicon, Inc.*, No. 8:20CV13, 2020 WL 3128748, at *3 (D. Neb. June 12, 2020). While that is true generally, in *Toman v. Creighton Mem. St. Josephs Hosp., Inc.*, 217 N.W.2d 484, 489 (Neb. 1974), the Nebraska high court distinguished between temporary and permanent medical conditions for purposes of determining whether the statute of limitation began to run. In that case, the court held that the limitation period on a medical malpractice claim did not begin to run when plaintiff experienced post-operative weakness in some extremities but her surgeon reassured her the weakness would disappear with the passage of time. The court concluded that "[u]nder the circumstances, we cannot hold that the statute of limitations began to run until the plaintiff could have discovered by the use of reasonable diligence that her resulting injury was permanent, as contrasted with a temporary post-operative injury." *Id.* As Somatics points out, *Toman* was decided in the context of the medical malpractice statute of limitation, but the Court finds the distinction it draws between temporary and permanent conditions applies here as well.

The Court also finds persuasive *Akkerman v. Mecta Corp.*, 72 F. App'x 652 (9th Cir. 2003). There, the appellate court reversed the district court's dismissal of

the plaintiffs' complaint against the manufacturer of an ECT device. The complaint alleged facts showing the husband-and-wife plaintiffs knew the husband suffered from memory loss outside the limitation period. The court pointed out, however, that they had been "warned that temporary memory loss was a possible side effect of the shock treatments, and that it was "Akkerman's permanent memory loss, and the resulting loss of consortium, that constitute plaintiffs' injuries." *Id*. at 654.

On the other hand, the facts presented here are distinguishable from those in *Minzel*, 2020 WL 3128748, relied on by Somatics. There, the plaintiff knew or should have known she had suffered an injury when, after surgical installation of a mesh device to treat urinary incontinence, she experienced continued incontinence, required repeat surgery due to exposed mesh in her vagina, and experienced painful intercourse. *Id*. at *1, 3. Regardless of whether those conditions continued or abated, the plaintiff there was already on notice she had suffered an injury from the device. While a jury might conclude the same is true on the facts presented here, the issue cannot be determined as a matter of law. Accordingly, Somatics' motion for summary judgment is denied as to this ground, and this affirmative defense will have to be decided by a jury.

Learned Intermediary

Somatics moves for summary judgment on Plaintiff's claims to the extent they are based on a failure to warn, arguing that even if Somatics failed to warn of the dangers attendant to treatment with its ECT device, it is entitled to prevail as a matter of law under the learned intermediary doctrine. Under the Nebraska

version of the learned intermediary doctrine, a prescription medical product manufacturer's duty to provide an adequate warning of a product's risks runs to the prescribing or treating physician, not to the patient, unless the manufacturer has reason to known that physicians will not be in a position to reduce the risks of harm in accordance with the warnings. *See Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 841-42 (Neb. 2000). It is up to the physician to evaluate the warnings in light of his or her independent medical knowledge and the specific medical condition and needs of the patient in order to decide on a course of treatment. *Id.* As corollary, a failure to provide an adequate warning is not the cause of a patient's injury if the prescribing physician had independent, actual knowledge of the dangers an adequate warning would have communicated and would have taken the same course of action even if provided with such a warning. *See, e.g.*, *Ideus v. Teva Pharm., USA, Inc.*, 361 F. Supp. 3d 938, 946 (D. Neb. 2019); *see also Brinkley v. Pfizer, Inc*, 772 F.3d 1133, 1137 (8th Cir. 2014) (applying Missouri law).

Somatics argues that Plaintiff's treating physicians, Drs. Sharma, Sadiq, and Askalaf, already knew based on their independent medical training, knowledge, and experience, that there was a risk of permanent memory loss with the use of ECT devices, including the Thymatron. The Court concludes, however, that the record presents issue of fact as to the level of the physicians' independent knowledge and as to whether the absence of an adequate warning contributed to Plaintiff's treatment and alleged injuries. For example, Dr. Sharma believed that permanent loss of memories, while a known risk, was rare, while Plaintiff's expert John Read

opines that a "substantial portion" of recipients, in the range of 12% to 55% percent, suffer persistent or permanent memory loss and brain damage as a result of treatment. Plaintiff's physicians also testified that they did not understand that ECT causes brain damage. Particularly given the parties' factual disputes regarding the actual risks posed by ECT treatment, an issue of fact exists as to whether Plaintiff's physicians were fully informed of the risks based on their independent medical knowledge, and as to what they would have done had they been advised of facts such as those testified to by Read.

Medical Causation

Somatics argues that Plaintiff has no competent, probative evidence that the ECT treatment caused permanent memory loss and brain damage. A plaintiff seeking to establish the causation element of a product liability claim must present expert testimony supporting both general causation and specific causation. *See King v. Burlington N. Santa Fe Ry. Co.*, 762 N.W.2d 24, 34 (Neb. 2009); *Grant v. Pharmavite, LLC*, 452 F. Supp. 2d 903, 907 (D. Neb. 2006).[3]

General causation refers to whether the drug or other product can cause the injury in question. General causation is established by expert testimony typically based on evidence such as the association between the product and injury shown in epidemiological studies, the strength and nature of the association, and the

[3] *See also Barrett v. Rhodia, Inc.*, 606 F.3d 975, 984 (8th Cir. 2010) (holding that expert evidence is required to establish both general and specific causation). "Expert testimony based on possibility or speculation is insufficient [to establish causation]; it must be stated as being at least 'probable,' in other words, more likely than not." *Id.*

biological plausibility of a causal relationship. *See King*, 762 N.W.2d at 34-42. Specific causation refers to whether the product did in fact cause the plaintiff's injury. *Id*. at 34. This is typically established by expert testimony employing a technique known as differential etiology (sometimes loosely referred to as "differential diagnosis"). *Id.* at 49-50. An expert employing this method first "rules in" possible causes of the patient's condition (based on a general causation analysis), and then "rules out" other potential causes based on additional evidence or tests, leading to a conclusion that the remaining possible cause more likely than not was the actual cause. *Id*.

As to general causation, Plaintiff relies on John Read, Ph.D., a professor of neuropsychology. Read has studied ECT treatment and reviewed the relevant literature. In his report, Read offers the opinion, expressly stated "to a reasonable degree of scientific certainty," that "ECT causes persistent/permanent memory loss and brain damage in a substantial proportion of recipients, somewhere in the range of 12% to 55%." Somatics has not moved to exclude any of Read's opinions as inadmissible under *Daubert* or Fed. R. Evid. 702. Plaintiff additionally relies on the opinions of Bennet Omalu, M.D., that ECT treatment causes injury to the brain (general causation), and that it did so in Plaintiff's case (specific causation). Somatics has challenged Dr. Omalu's general causation opinion as unreliable under Fed. R. Evid. 702 and *Daubert*, and its admissibility remains to be determined.

Somatics argues that Read cannot opine "to a reasonable degree of medical certainty" that ECT can cause the types of injuries Plaintiff sustained because he

stated in his deposition that there is a lack of scientific studies demonstrating ECT's capability of causing the injury. In context, however, Read's testimony referred only to a lack of adequate studies demonstrating ECT's efficacy, not its capability of causing injury. Nebraska law requires expert evidence to be *stated* as a matter of reasonable probability (i.e., "more likely than not") rather than mere possibility or speculation. *See, e.g., Fackler v. Genetzky*, 638 N.W.2d 521, 527-28 (Neb. 2002). Read states his opinion with the requisite degree of certainty, and Somatics filed no *Daubert* motion challenging the reliability of Read's opinions.

Plaintiff's experts on specific causation are Dr. Omalu, a medical doctor, and Mark Hannappel, Ph.D., a psychologist. Somatics argues that both experts' opinions must be excluded for the reasons set forth in tits *Daubert* motions. While the Court agrees as to Hannappel, the Court has ruled Dr. Omalu's specific causation opinions are admissible, deferring a ruling only as to whether he will be allowed to opine as to general causation. Accordingly, it appears Plaintiff will be able to present admissible expert evidence at trial as to both general causation (Read and possibly Omalu) and as to specific causation (Omalu). Somatics' summary judgment motion is therefore denied as to this ground.

Implied Preemption

Somatics argues that aspects of Plaintiff's negligence claim asserted in Count I of the complaint are preempted based on 21 U.S.C. § 337(a). That statute provides that actions to enforce FDA requirements "shall be by and in the name of the United States." Therefore, claims that seek to enforce duties that run to the FDA

are impliedly preempted. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 348 ("[P]laintiffs' state-law fraud on the FDA claims conflict with, and are therefore impliedly preempted by, federal law."); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017). On the other hand, state law negligence claims are not preempted simply because they rely on a violation of a federal statute or safety regulation as evidence that the defendant violated a duty of care. *See, e.g.*, *Clark Bilt, Inc. v. Wells Dairy Co.,* 261 N.W.2d 772, 775 (Neb. 1978); *Raab v. Smith & Nephew, Inc.*, 150 F. Supp. 3d 671, 689 (S.D.W. Va. 2015) ("Claims such as negligence and strict products liability often use the violation of safety statutes to demonstrate that traditional state law duties, such as the duty of reasonable care . . . have been breached.").

Paragraph 68 of Plaintiff's negligence count asserts that Somatics owed to Plaintiff and the public a duty to use reasonable care in, among other things, researching, manufacturing, analyzing, testing, selling, and labeling its ECT devices, including the Thymatron device. Six subparagraphs then point to various violations of that duty. Somatics asserts implied preemption as to the allegations in subparagraphs (iii), (iv), and (v). Some of these rely on duties running solely to the FDA, while others do not.

Paragraph 68(iii) asserts that Somatics failed to adequately investigate reports of serious adverse events. This subparagraph does not refer to the FDA or to any federal statute and regulation and does not implicate implied preemption. *See O'Neill v. Somatics, LLC*, No. 20-cv-175-B, 2022 WL 4611938, at *7 (D.N.H.

Sept. 30, 2022) ("[T]o the extent that O'Neil argues that Somatics was negligent for failing to adequately investigate reports of adverse events from the use of ECT, her claim is clearly not preempted because it is ground in state tort law that does not depend on any federal requirement.").

Paragraph 68(iv), in contrast, alleges Somatics failed to adequately report adverse events to the FDA. This allegation seeks to enforce a duty that runs to the FDA and is therefore impliedly preempted. *See Mink*, 860 F.3d at 1330.

Paragraph 68(v) alleges that Somatics violated federal statutes and regulations "including but not limited to" 21 C.F.R. §§ 803.01 to 803.23, § 803.50-803.58; 21 C.F.R. 820.198; and 21 C.F.R. § 807.20. These provisions impose reporting and record keeping requirements. They involve duties running to the FDA under federal law, rather than duties owed to Plaintiff under state law and as such are impliedly preempted. *See, e.g.*, *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (allegations of defendants' "failure to adhere to the FDA regulations on recordkeeping, labeling, design validation and establishment and maintenance of complaint file" were impliedly preempted).

Accordingly, the Court grants Somatics' motion for summary judgment as to the negligence claim to the extent the claim is based on the allegations in paragraph 68(iv), and the cited regulations in paragraph 68(v). The motion as to this ground is otherwise denied.[4]

[4] To the extent that Plaintiff may attempt at trial to rely on some other federal statute or regulation not specifically identified in the complaint, Somatics is free to raise preemption in addition to any other arguments it may have, including waiver.

Manufacturing Defect

"A manufacturing defect exists when the product differs from the plan and specifications of the manufacturer." *Freeman*, 618 N.W.2d at 841. Somatics argues that Plaintiff has presented no evidence or argument that the devices used to treat him contained manufacturing flaws causing the specific models to deviate from the intended design or specifications. Plaintiff has not responded to this point, and indeed based on the pleadings and other filings, it does not appear to the Court that Plaintiff even asserts a manufacturing defect claim. To the extent he does, summary judgment is granted in favor of Somatics on this ground.

Express Warranty

Somatics argues that Plaintiff has no evidence of an express warranty. An express warranty requires a representation by the defendant that becomes the basis of the bargain between the person giving the warranty and the person purchasing the product. *See id*. at 844. Because an express warranty must be made a part of the basis of the bargain, a plaintiff must prove reliance on the warranty. *E.g., Hillcrest Country Club v. N.D. Judds Co.*, 461 N.W.2d 55, 61 (Neb. 1990). Somatics argues there is no evidence of any representation or warranty by Somatics relied on by Plaintiff or by the hospital that purchased the ECT devices, or otherwise made a part of any relevant "bargain." Somatics argues that Plaintiff bases the alleged warranty on statements made on Somatics' website, but no witness has stated he or she relied on these representations or even looked at the website. Plaintiff has not responded to this argument. The Court finds Somatics' argument to be well taken.

Accordingly, summary judgment is granted for Somatics on Plaintiff's express warranty claim in Count V.

Design Defect

Somatics argues that Plaintiff has presented no evidence to support his claim for design defect. In the context of prescription drugs, the Supreme Court of Nebraska has held that design defect claims are evaluated under the "consumer expectations" test. *See Freeman*, 618 N.W.2d at 840. This test focuses on whether the product is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id*.

Somatics contends Plaintiff has failed to present evidence regarding "consumer expectations." Plaintiff argues, and the Court agrees, that the relevant "consumers" are patients, rather than physicians, even in cases involving prescription products. *See id*. Plaintiff, however, offers no evidence, argument, or supporting authority to establish the expectations of an "ordinary consumer" with the "ordinary knowledge common to the community" about ECT devices. Instead, Plaintiff points to his own expectations, which may or may not reflect the "ordinary knowledge common to the community," and to specific criticisms regarding features of the device, which are relevant to a risk/benefit analysis rather than to the consumer expectations test. Accordingly, Somatics' motion for summary judgment is granted as to this ground.

Punitive Damages

Somatics argues that Plaintiff has no evidence sufficient to support a jury award of punitive damages under the standards imposed by § 768.72, *F.S.* for such awards.[5] Under that statute, a plaintiff must show "intentional misconduct," which requires that the defendant had actual knowledge of the wrongfulness of the conduct and of the high probability that injury to the claimant would result from the conduct, or "gross negligence," meaning that the defendant's conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the safety of persons exposed to the conduct.

Significantly, the statute also requires that the requisite conduct be established by clear and convincing evidence. Such evidence "must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established." *Slomowitz v. Walker*, 429 So. 2d 797, 800 (Fla. 4th DCA 1983). To avoid summary judgment, Plaintiff must point to evidence that would allow a reasonable jury, applying the clear and convincing standard, to find that punitive damages are appropriate. *See Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 255-56 (1986) (holding that whether the summary judgment inquiry must be guided by the substantive evidentiary standard applicable at trial).

In support of his punitive damage claim, Plaintiff argues that Somatics failed to provide any warnings to Plaintiff or his physicians regarding risks of ECT

[5] The Court previously ruled that Florida law governs the punitive damages issues in this case. (Doc. 40).

treatment, that Somatics' owners in 2006 considered including a warning on the risk of permanent memory loss but decided against it for fear of "alienat[ing] psychiatrists," and that, despite knowing of hundreds complaints about cognitive impairment and permanent memory loss, Somatics has never performed any studies or tests to analyze the long term side effects of ECT. Somatics, on the other hand, points to the fact that the risks of ECT were widely discussed in published medical literature, to which Somatics referred purchasers, and that purchasers and users of the Thymatron ECT device were knowledgeable and aware of the risks and benefits.

Given the conflicting evidence and inferences that could be drawn, the nature of the product and its history, the knowledge of its purchasers and users generally and the studies and medical literature available to them, the Court concludes the evidence is insufficient to allow a reasonable juror to find by clear and convincing evidence that Somatics or any agent or employee acted with the requisite level of culpability. *See ADT LLC v. Safe Home Sec. Inc.*, No. 20-23918-CIV, 2022 WL 2805252, at *6 (S.D. Fla. May 18, 2022) (granting summary judgment on punitive damages where "the evidence, viewed together, does not evince, by a clear and convincing standard, the sort of gross, flagrant, and reckless or wanton conduct required to support punitive damages under Florida's heightened standard."). Summary judgment is therefore granted as to this ground.

Accordingly, it is hereby

ORDERED, ADJUDGED, and **DECREED:**

(1) The "Motion by Somatics, LLC for Final Summary Judgment" (Doc. 78) is **GRANTED IN PART** and **DENIED IN PART**.

(2) Summary judgment is **GRANTED** in favor of Defendant Somatics, LLC, and against Plaintiff Jeffrey Thelen on Plaintiff's negligence claim in Count I based on failure to report adverse events to the FDA (¶ 68(iv)), and failure to comply with certain federal regulations (¶ 68(v)).

(3) Summary judgment is **GRANTED** in favor of Defendant Somatics, LLC, and against Plaintiff Jeffrey Thelen on Plaintiff's express warranty claim in Count V.

(4) Summary judgment is **GRANTED** in favor of Defendant Somatics, LLC, and against Plaintiff Jeffrey Thelen on any claim for manufacturing defect.

(5) Summary judgment is **GRANTED** in favor of Defendant Somatics, LLC, and against Plaintiff Jeffrey Thelen on any claims for punitive damages.

(6) Defendant Somatics, LLC's motion for summary judgment is otherwise **DENIED**.

(7) Final judgment will be entered following disposition of all claims.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 5th day of May, 2023.

TOM BARBER
UNITED STATES DISTRICT JUDGE